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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/921,844

08/03/2001

Gary K. Michelson

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

11/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/921,844	Applicant(s) MICHELSON, GARY K.	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 19-56, 203-204, 207-209, 219, 228-254, 259-271, 277-284 (all claims) is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/25/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3, 5, 19-56, 203-204, 207-209, 219, 228-254, 259-271, 277-284 (all claims).

DETAILED ACTION

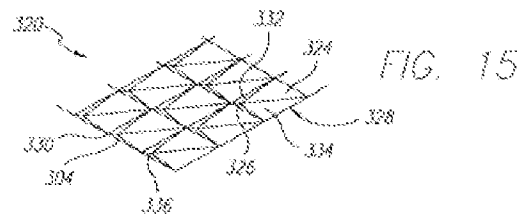
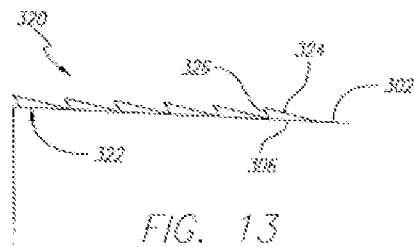
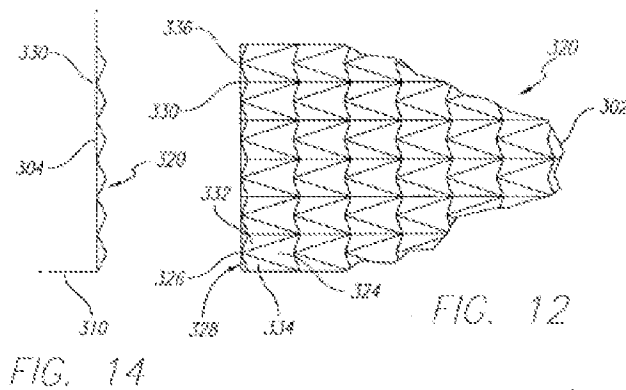
Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/05/10 has been entered.

Response to Arguments

Applicant's arguments filed 10/05/10 have been fully considered. The declaration filed on 10/26/10 under 37 CFR 1.131 has been considered but is ineffective to overcome the combination rejections relying on Fraser (6,592,624).

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the unidentified reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Applicant has failed to satisfactorily provide evidence to establish a conception of the invention prior to the effective date of the Fraser reference. Applicant's elected embodiment is shown in figures 12-15 is reproduced below:



It is the examiner's position that exhibits A-C fail to teach all the claim limitations of the elected embodiment. In fact exhibits A-C do not show the elected embodiment. Regarding claim 1, exhibits A-C fail to teach all the claim limitations. Applicant's description of the evidence reads:

"D). At least a portion of the reward facet of the first surface projection overlies a portion of the forward facet of the second surface projection (see Exhibit D)."

The examiner notes that applicant only indicates that exhibit D supports claim 1.

Regarding claim 219, applicant's description of the evidence reads:

"The forward facet has a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet being greater than the maximum length of the base (see Exhibit D)."

"The first included angle is greater than the second included angle (see Exhibit D)."

The examiner notes that applicant only indicates that exhibit D supports claim 219.

It is the examiner's position that only exhibit D supports some portion of either claim 1 or 219. Exhibit D is a copy of the drawings from the U.S. application; this copy is considered a conclusion and not satisfactory evidence of to establish a conception of the invention prior to the effective date of the Fraser reference. See MPEP 715.07.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Fraser reference. Applicant has failed to satisfactory evidence to establish a reduction to practice of the invention prior to the effective date of the Fraser reference. It is the examiner's position that only exhibit D supports some portion of either claim 1 or 219. Exhibit D is a copy of the drawings from the U.S. application; this is considered a conclusion and not satisfactory evidence of to establish a reduction to practice of the invention prior to the effective date of the Fraser reference. See MPEP 715.07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

All claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, "said base of said perimeter of each of said side facets being longer than said base of said perimeter of said forward facet" is not understood. Please diagram.

Claim 1 claims "a plurality of surface projections.. each having at least one forward facing facet". The claim further claims "each of said forward facets" which is unclear. Is this describing each of the more than one forward facet on each projection? Or, is it describing each of at least one forward facing facet on every projection? Same for claim 219.

Claims 1 and 219, how is the length of the facets measured? Along the surface of the facet or parallel to the surface of the implant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 19-56, 203, 204, 207-209, 219, 228-254, 259-271, 277-284 (all claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No. 7,115,143. Although the conflicting claims are not identical, they are not patentably distinct from each. The patent claims are broadly directed to an orthopedic implant whereas the current claims are directed to the specific, a spinal implant. One having ordinary skill in the art recognizes a spinal implant is type of orthopedic implant and would have been obvious to have tried. The remaining limitations are directed to the same configuration of surface projections.

Claims 1, 3, 5, 19-56, 203, 204, 207-209, 219, 228-254, 259-271, 277-284 (all claims) are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No. 7,244,727. Although the conflicting claims are not identical, they are not patentably distinct from each. The patent claims are broadly directed to an orthopedic implant whereas the current claims are directed to the specific, a spinal implant. One having ordinary skill in the art recognizes a spinal implant is type of orthopedic implant and would have been obvious to have tried. The remaining limitations are directed to the same configuration of surface projections.

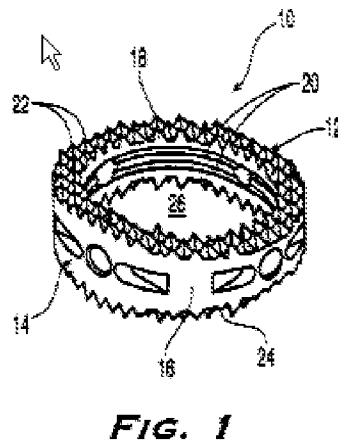
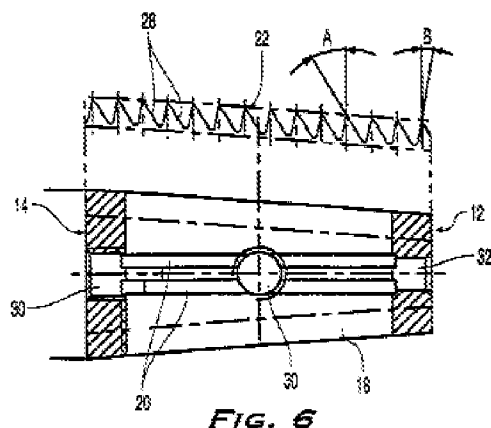
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

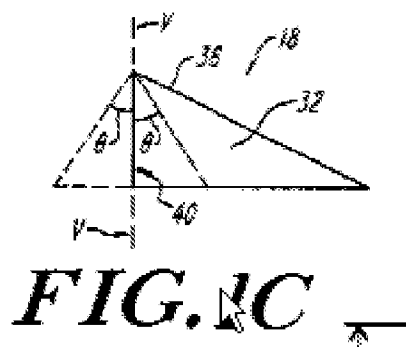
Claims 1, 3, 5, 19-56, 203, 204, 207-209, 219, 228-254, 259-271, 277-284 (all claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Abei et al (6,482,233) in view of Fraser (6,592,624).

Referring to figure 6, **Abei et al** teaches a teaches a spinal implant comprising a plurality of pyramid-shaped projections 28 formed on the upper and lower surfaces of the implant which are slanted to *“allow for ease of insertion and avoid retroplusion after insertion (4:30 et seq.)”*



The projections are slanted towards the trailing end 14, therefore, having a forward facing facet which is longer than a rearward facet. The projections further include side facets and a rectangular base. However, Abei et al is silent regarding the length of the forward facing facet having a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet greater than the maximum length of the base.

Referring to figure 1C, Fraser teaches a similar spinal implant having surface projections 18 wherein the rearward facet 34 can either have a positive slope or negative slope.



It would have been obvious to one having ordinary skill in the art to have formed the rearward facet of Abei et al forming a negative slope such that the length of the forward facing facet is greater than the maximum length of the base such that the projections dig into the bone and better resist expulsion. Therefore, the maximum length of the forward facet is greater than the maximum length of the base (claim 219).

Regarding claim 219, it is noted that Fraser fails to specifically teach a projection with four facets, but states "*although fins 18 are described and illustrated as having a substantially wedge-shape with a triangular profile, one of ordinary skill in the art will appreciate that other shapes may be used as well*". This Examiner does appreciate that; to have more than three, as illustrated, is not patentable subject matter.

Regarding claim 1, with the rearward facet having a negative slope, the adjacent projections of Abei et al would produce "at least a portion of said rearward facet of the first surface projection overlying a portion of said forward facet of said second surface projection". It is the Examiner's position that one skilled in the art would have kept the projections immediately adjacent as taught by Cottle to produce a higher density of projections per area to better resist repulsion. Results would have been predictable. Further see at least SU 1107854 teaching such spacing is known in the art.

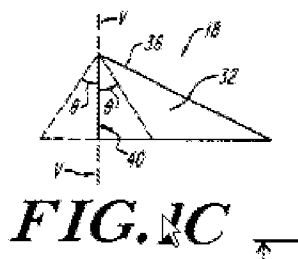
Many of applicant's dependent claims claim a wide range of limitations, for example, elements/materials/shapes/tools/etc which lack criticality in the specification, the use of any limitations in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design

choice for someone skilled in the art. Additionally, these limitations are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Additionally, it would have been obvious to one having ordinary skill to have used any bone growth material known in the art or to have constructed the implant from any material known in the art for their known properties and characteristics.

Claims 1, 3, 5, 19-56, 203, 204, 207-209, 219, 228-254, 259-271, 277-284 (all claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraser (6,592,624) in view of Paul et al (6,258,125) and further evidenced by SU 1107854 (applicant provided 10/21/05) and Cottle (5,88,227).

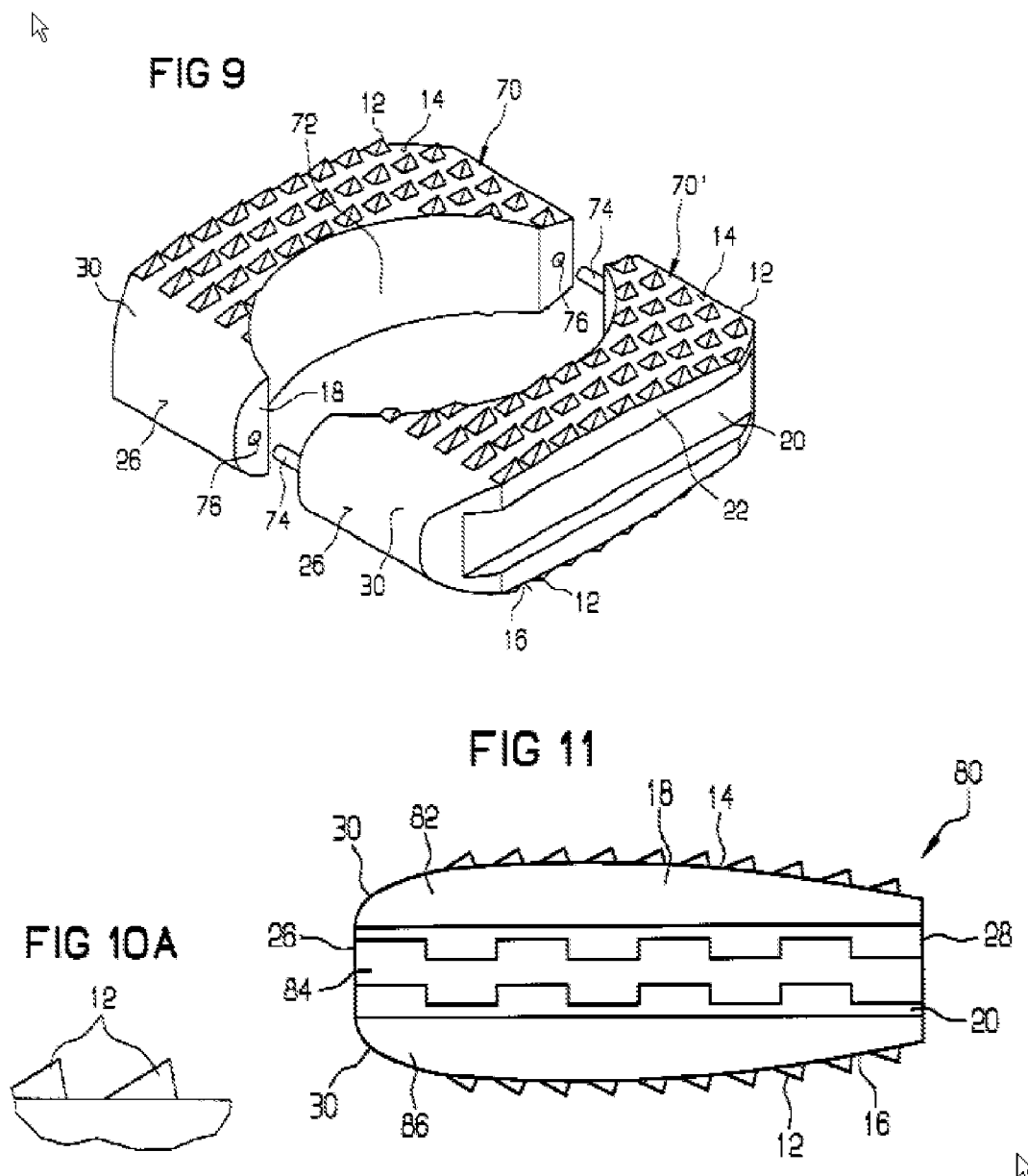
Referring to figure 1C, Fraser teaches a spinal implant having surface projections 18 wherein the rearward facet 34 can either have a positive slope or negative slope.



Fraser states:

(12) Although fins 18 are described and illustrated as having a substantially wedge-like shape with a triangular profile, one of ordinary skill in the art will appreciate that other shapes may be used as well. It is also understood that the dimensions, i.e., height, length, and width of the fins may vary, as may the overall geometry of the fins.

Paul et al also teaches a spinal implant having projections with four facets as shown in figures 9, 10A, and 11.

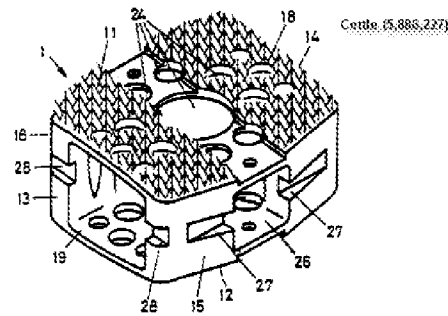
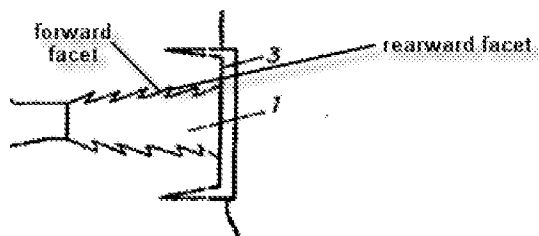


It would have been obvious that one skilled in the art would have appreciated that the "other shapes" and "overall geometry of the fins" would include four faceted projections as taught by Paul et al with predictable results. This would have produced

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the projection as claimed in applicant's claim 219 wherein the length of the forward facing facet having a maximum length as measured along a line parallel to the maximum length of the base, the maximum length of the forward facet greater than the maximum length of the base.

Regarding claim 1, Fraser et al teaches, "fins 18 may vary in shape, number, and in their placement on either or both of the end plates 12, 14." It is the Examiner's position that it would have been obvious to one skilled in the art would have positioned the projections immediately adjacent as taught known in the art to produce a higher density of projections per area to better resist repulsion. Results would have been predictable. See at least SU 1107854 (applicant provided 10/21/05) and Cottle (5,88,227) as evidence of higher density of projections is known in the art.



Many of applicant's dependent claims claim a wide range of limitations, for example, elements/materials/shapes/tools/etc which lack criticality in the specification, the use of any limitations in lieu of those used in the references solves no stated problem and produces no benefits and would have been an obvious matter of design choice for someone skilled in the art. Additionally, these limitations are well known in the prosthetic art and would have been obvious to one having ordinary skill.

Additionally, it would have been obvious to one having ordinary skill to have used any bone growth material known in the art or to have constructed the implant from any material known in the art for their known properties and characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce E Snow/

Primary Examiner, Art Unit 3738